HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service D1109B
JEW 1/17/97

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-16

January 16, 1997

Melanie Materazzi, President
Citi Pharmaceuticals, Inc.
7308 S.W. 48th Street
Miami, Florida 33155

Dear Ms. Materazzi:

This letter is written in reference to your firm's manufacturing and distribution of Friatroy, an herbal product offered for, among other claims, the reduction of tumor mass, decrease in tumor markers, decrease in asthenia, reduction in pain, and as a diuretic.

Friatroy is a drug within the meaning of Section 201(g) of the Food, Drug, and Cosmetic Act (the Act) based on claims for specific disease conditions made in the labeling (the product information sheet). It is also a "new drug" within the meaning of Section 201(p) of the Act due to the lack of any evidence that this product is generally recognized as safe and effective for its intended use and may not be marketed without an approved New Drug Application (NDA) pursuant to Section 505 of the Act.

The drug is also misbranded within the meaning of Sections 502(a) and 502(f)(1) of the Act because the labeling is false and misleading and fails to bear adequate directions for use.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

For your information, the published advertisements for conference(s)/seminar(s) that state that doctors will speak about Friatroy for the treatment of cancer and HIV/AIDS are promotions of Friatroy for these diseases. We are unaware of any general recognition of Friatroy as safe and effective for these uses. Therefore, Friatroy requires an approved NDA prior to marketing for the treatment of cancer or HIV/AIDS.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, attention: Jimmy E. Walthall, Compliance Officer, telephone (407) 648-6823, extension 263.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District